Supplemental Information and Clinical Guidance for DoD Depleted Uranium (DU) Medical Management Program

July 2007

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Background

This document was prepared by the DoD Deployment Health Clinical Center (DHCC) to provide clinical guidance for healthcare providers on the DoD Depleted Uranium (DU) Program. References used in the preparation of this document are listed in Appendix A. These references and additional information on depleted uranium can be found on the DHCC DU web page www.pdhealth.mil/du.asp

Identification of DU-Exposed Personnel

There are two primary methods of identification of personnel potentially exposed to DU: proactive and reactive.

- Proactive. The Services have been directed to identify units and the personnel assigned to
 units that could have been exposed to DU using information about events involving DU
 munitions or other DU containing materials that may have resulted in internal exposure to
 DU. Identification of members in these groups and detailed descriptions of the possible
 exposure conditions provide valuable information for verifying that potentially exposed
 individuals are being identified and evaluated.
- 2. Reactive. The majority of personnel are most likely to be identified by reactive methods through individual self-report. These methods include:
 - a. Positive response to Questions 14, 17, and 18 on the <u>DD Form 2796, Post-Deployment Health Assessment</u> (PDHA) during redeployment;
 - Self-report of patients to operational medical assets in-theater;
 - c. Self-report or clinical reports of patients entered into the air-evacuation system for either DU wounds or other medical reasons; and
 - d. Self-report of patients in primary care clinics under the <u>Post-Deployment Health</u> Evaluation and Management Clinical Practice Guideline (PDHCPG).

Assessment of DU-Exposed Personnel

- 1. History of Potential DU Exposure. Healthcare providers with the assistance of the individuals being assessed for DU exposure will complete the <u>DoD DU Questionnaire</u> and <u>Health Survey</u>. These forms are currently available as DoD Test Forms (<u>DD Form 2872 Test</u> and <u>DD Form 2872-1 Test</u>). In the future these two test forms may be overprinted on a single Standard Form SF-600. The DoD DU Questionnaire is a modification of the DU questionnaire used by the VA (VA Form 10-9009D). The Health Survey is a short measure of health-related functioning comprised of 36 questions asking the patient to describe physical or emotional problems over the past four weeks. These forms can be downloaded from the DoD Deployment Health Clinical Center (DHCC) website, <u>www.pdhealth.mil</u>. The healthcare provider along with the individuals being evaluated will review the completed forms and any other supporting information, such as incident reports or description of potential exposure conditions.
- 2. Categorization of DU Exposure. Based on the history provided on the <u>DoD DU</u>

 <u>Questionnaire</u> and other available supporting information, the healthcare provider will assign the individual to one of three DU exposure categories: Level I, II, or III.
 - a. Level I. This exposure level is assigned to all individuals who were believed to be struck by DU munitions or DU armor fragments. In addition, it includes those who were in, on, or less than 50 meters from an armored vehicle at the time it was struck by munitions believed to contain DU and to first responders who entered these vehicles to render aid to the crewmen. These personnel may exceed peacetime standards for internal exposures to DU. Urine DU bioassays are required for all personnel within this exposure level. For hospitalized Level I patients, bioassays are to be administered on a priority basis as soon as their medical condition permits collection of a complete 24-hour urine sample. Other Level I personnel will have bioassays performed as soon as possible, even if the most ideal testing period, within 180 days post-exposure, has been exceeded.
 - b. Level II. This exposure level is assigned to those personnel, other than first responders, who routinely entered vehicles possibly containing DU residues to perform maintenance and recovery operations, intelligence operations, or battle-damage assessments. This exposure level also includes individuals whose occupation required them to fight fires involving DU-containing materials. Personnel in this level may exceed peacetime standards for occupational exposures to DU. Urine DU bioassays are required for all personnel with this level of exposure. The bioassays should be performed as soon as possible, even if the most ideal testing period, within 180 days post-exposure, has been exceeded.
 - c. Level III. Level III exposures are those which are incidental in nature. Incidental DU exposures would not likely result in any significant uptake of DU into the body. Examples of Level III exposures include infrequently and only for short periods entering or climbing on or into battle-damaged vehicles or breathing smoke from fires involving DU materials. Bioassays are not required for personnel in this level, though a physician may choose to perform one based on medical indications or on potentially exposed individual's request.
- 3. Health Risk Communications. Healthcare providers are responsible for providing appropriate health risk communications to patients presenting with DU concerns. Patients will be informed of the reason they are being evaluated for DU, the timelines and nature of the assessment process, the potential individual risk or likelihood of

identification of DU exposure, the generally low incidence of significant DU exposure in theater, and the medical follow-up that is available. Providers should demonstrate awareness of potential concerns that patients have regarding potential DU exposure and should communicate, both in content and process, information that will ensure that patients are fully informed and are reassured about the process and potential outcomes. Information and fact sheets on DU and DU testing can be found on the DHCC DU web page, www.pdhealth.mil/du.asp. For guidance on effective risk communication procedures, providers are directed to contact Service-designated subject matter experts, the DHCC, or the VA DU Follow-up Program staff included at Appendix B.

4. The original copies of the completed <u>DoD DU Questionnaire</u> and <u>Health Survey</u> will be filed in the patient medical record.

Urine DU Bioassay Procedures

- 1. DU Testing. Urine bioassay for total uranium analysis and DU isotopic analysis constitutes one component in the evaluation of potential exposure to depleted uranium; and the results provide an indicator of the need for further medical follow-up. HA Policy 03-12 directs collection of urine specimens for uranium testing within 180 days of a potential exposure incident. Every effort should be employed to identify and evaluate personnel who may have been exposed to depleted uranium throughout the deployment cycle according to this guidance. Testing within the 180-day window increases ability to detect lower level exposures. Nevertheless, urine excretion of uranium continues after the 180 days, and collection of urine samples for initial evaluation of depleted uranium exposure should be accomplished even when the earliest possible testing opportunity presents after the recommended 180-day period.
- 2. Sample Handling. For those patients requiring a urine DU bioassay, a Lab Request Specimen Tracking Form, contact information for both the patient, the ordering provider, and the Primary Care Manager (or primary care provider at the military treatment facility at the patient's station of assignment), will be forwarded with all urine samples. Care must be taken to ensure that urine specimen containers are free of uranium contamination. Testing laboratories should be contacted for shipping instructions and for information regarding the type of container to use. Each laboratory request for urine DU bioassay will include name. SSN, age, sex, height, and weight of the individual: dates of exposure; the date and start and stop times of urine collection. The sample must be identified as an initial 24-hour, initial spot, 710 day sample, or a repeat sample. The request should specify that a urine total uranium and uranium isotopic analysis be run and that the results be normalized to urine creatinine with results expresses as nanograms of uranium/qm of urine creatinine, and that results also be normalized to the volume of urine with results expressed as nanograms of uranium per liter of urine. It is permissible for the collecting lab to do the urine creatinine test if they have the capability. In this case, those results must be forwarded along with the urine specimen. Isotopic analysis is the specific test used to identify the fraction of the urine uranium is contributed by DU. Copies of all the exposure assessment and health survey forms must accompany the urine samples.
- 3. Service-specific Procedures. For both urinary uranium and creatinine testing, each Service has developed processes for collecting, tracking, shipping, and processing samples, reporting results to patients and providers, and ensuring that all pertinent documentation is forwarded to DHCC for archiving. Army specimens are sent to the US Army Center for Health Promotion and Preventive Medicine (USACHPPM) for testing. Air Force specimens are sent to the Air Force Institute for Operational Health (AFIOH) Radioanalytical Branch, Radiation Surveillance Division which coordinates with the Baltimore VA Medical Center DU Follow-Up Program to have the specimens tested. Navy/Marine specimens are sent to the Baltimore VA Medical Center DU Follow-Up Program. The Baltimore VA Medical Center DU Follow-Up Program sends all specimens to the Armed Forces Institute of Pathology (AFIP) for testing. The DU Program policies and forms used by each service are referenced in Appendix A. For information and assistance regarding DU testing, a list of Service-specific DU Program Points of Contact is in Appendix B.
- 4. Laboratory Procedures, Quality Assurance and Quality Control.

- a. Testing Methodology. Several analytical methods are available for determining the isotopic uranium content in urine. Isotopic analysis is necessary to determine whether any uranium detected in the urine is entirely natural uranium or has a depleted uranium component. Based on experience from evaluating depleted uranium exposures in Operation Desert Storm, analysis of uranium-235 and uranium-238, are indicated and are best-performed using mass spectrometry, generally Inductively Coupled Plasma Mass Spectrometers that deliver adequate sensitivity.
- b. Quality Assurance/Quality Control. Accurate and reliable analytical results are vitally important for the uranium assessments. Laboratories performing the analyses must have documented calibration and quality assurance programs for demonstrating reliable performance. In addition, the laboratories should validate internal quality assurance results by participating in intercomparison programs or similar evaluations in collaboration with qualified, independent laboratories. Documentation of all quality assurance activities must be maintained and made available for review by oversight agencies, such as the Deployment Health Support Directorate. Copies of all such documentation will be sent to the Deployment Health Support Directorate, when requested. In accordance with the Assistant Secretary of Defense Memorandum dated 9 April 2004, laboratories performing DU urine bioassays should store a 250 ml aliquot of the urine tested indefinitely.

Results Reporting and Records Management

Results Reporting. The processing lab will forward results of the urine DU bioassay to the provider who ordered the DU urine bioassay as indicated on the lab request and specimen tracking form. A confirmatory 24-hour sample collection will be ordered based on the Protocol for DU Urine Validation Testing and Referrals to the Baltimore VA Follow-up Program at Appendix C. Along with the lab results, the provider will receive a letter with further information, including interpretation and health risk communication guidance in communicating results to those providing the urine specimens. In addition, the provider will be instructed to contact a subject matter expert (SME) at the processing lab for further guidance on interpretation and presentation of results to the patient.

Patient Notification of Results. The provider will be responsible for providing detailed results to the patient. (In addition, for Air Force, Navy and Marine patients tested through the VA, the VA will forward a letter with the results directly to the patient.) The provider will deliver results to the patient using the appropriate health risk communication guidance included in HA Policy 03-12 and also available on the DHCC web site, http://www.pdhealth.mil/. The provider will document delivery of the results in the medical record, ensure that the lab results are filed in the medical record, and make arrangements for referral for follow-up care, as necessary. For active duty service members who have changed duty locations and for reserve component service members, the provider will coordinate with the Patient Administration Division to ensure that the DU test results are forwarded to a provider at the service members' new location.

Medical Management

- 1. Baltimore VA DU Follow-up Program.
 - a. Referral Process. In reviewing results of the evaluation and urinalysis for possible enrollment in the VA follow-up program, providers will refer to the Protocol for DU Urine Validation Testing and Referrals to the Baltimore VA Follow-up Program at Appendix C. Patients with confirmed positive urine DU bioassay results, as defined in the attached protocol, will be offered referral to the Baltimore VA DU Follow-up Program. All referrals to the VA must be coordinated through the DHCC. Service members will be referred to the VA Program using a SF513, Consultation Sheet, a copy of which will be maintained in the medical record.
 - b. Scheduling and Funding Referral. Patients will consult with their PCM/primary care provider and with command personnel to determine timing and procedures for attendance in the VA Program. Operational considerations will take precedence in determining program attendance, but initial follow-up should begin no later than (NLT) six months post-identification. Funding for participation in the Baltimore VA program, including TDY costs, will be the Services' responsibility.
 - c. Enrollment in the VA DU Follow-up Program consists of an initial 2.5-day inpatient evaluation. Patients will be offered follow-on services for ongoing assessment and medical management based on the outcome of the initial assessment. Continued follow-up program attendance is recommended every two years. Upon completion of services, the VA will document the services provided to the patient on the SF513 and through narrative summary and will provide the documentation to the referring provider for inclusion in the medical record and a copy to DHCC for archiving.

2. Military Health System Continuing Medical Management. Service members with positive DU exposures, as determined by urine DU bioassays, historically have been asymptomatic. Periodic assessment and medical management will be provided through the VA Program at 2-year intervals. The military health system will continue to provide on-going medical management for service member health concerns through standard primary care services following the DoD/VA Post-Deployment Health Evaluation and Management Clinical Practice Guideline. In addition, reported health concerns and progress of care through the VA Program will be assessed during regularly scheduled Periodic/Preventive Health Assessments and Physical Exams.

Surveillance and Tracking

The Services will establish procedures to collect, maintain, and track details of all personnel potentially exposed to DU, the results of their evaluations, and any medical follow-up. Information on exposure conditions will be collected and maintained in sufficient detail to fully characterize the exposure for use in follow-on investigations, evaluations, and health risk assessments. That information should be compared with servicemembers identified with incidents, reports of duties involving possible contact with DU-contaminated equipment or facilities, and other methods to assure appropriate evaluations are being performed.

Records Archiving

DHCC will provide a central archive for all patient information related to DU exposure, testing, and follow-up for both active duty and reserve component personnel. Assessment questionnaires, lab results, referral consults, and narrative summaries from follow-up care will be forwarded to DHCC for archiving. Service Labs and the Baltimore VA will forward all DU health care documentation to DHCC for archiving following completion of DU-related health services.

OIF DU Exposure Semi-Annual Progress Report

In order to assess the impact of the DU Policy and to more closely monitor the numbers of personnel with documented exposures to DU, the Assistant Secretary of Defense for Health Affairs issued ASD(HA). Memorandum, Operation Iraqi Freedom Depleted Uranium Medical Management, 9 Apr 04 which requested the initial reporting of the Service's DU urine bioassay results to the Deployment Health Support Directorate by 9 May 2004. ASD(HA) Memorandum, Operation Iraqi Freedom Depleted Uranium Bioassay Results and Semi-Annual Data Submission, 10 Sep 04 requested a second semi-annual submission for the period April 2004 - September 2004 and subsequent submissions every six months from that date. It also provided slightly revised data tables for the submission of the DU data in Appendix D.

Appendix A: References

- 1. Department of Defense DU Policies
 - a. HA Policy 03-012, Policy for OIF DU Medical Management, 30 May 03
 - b. <u>HA Policy 04-004, Department of Defense Deployment Biomonitoring Policy and Approved Bioassays for Depleted Uranium and Lead, 6 Feb 04</u>
 - c. <u>ASD Memorandum, Operation Iraqi Freedom Depleted Uranium Medical Management,</u> 9 Apr 04
- 2. Service-specific DU Policies
 - a. Army OTSG/MEDCOM Policy Memo 07-022, Medical Management of Army Personnel Exposed to Depleted Uranium (DU), 26 Jun 07
 - b. Air Force CENTAF Memorandum, Air Force Medical Service Policy on Operation IRAQI FREEDOM Depleted Uranium (DU) Medical Management (SG Policy Letter #03-003), 25 Aug 03
 - c. Navy/Marines <u>BUMEDINST 6470.10B</u>, <u>Initial Management of Irradiated or</u> Radioactively Contaminated Personnel, Enclosure 8, 26 Sep 03
- 3. Department of Veterans Affairs (VA) DU Policies
 - a. VHA Handbook 1303.1Evaluation Protocol for Gulf War and Iraqi Freedom Veterans with Potential Exposure to Depleted Uranium, September 2, 2004
 - b. VHA Handbook 1303.4 Evaluation Protocol for Non-Gulf War Veterans with Potential Exposure to Depleted Uranium (DU), September 2, 2004
- 4. Department of Defense DU Forms
 - a. DD Form 2872 Test, Depleted Uranium (DU) Questionnaire, Feb 2004
 - b. DD Form 2872-1 Test, Health Survey, Feb 2004
- 5. Service-specific DU Forms
 - a. <u>Air Force Version of Attachment B: Depleted Uranium Program Checklist, 24-Hour Urine Uranium Collection for Baltimore VA Medical Center, Consult Urine Instructions (Revised 07/03)</u>
- 6. VA DU Forms
 - b. VA Form 10-9009D. Depleted Uranium (DU) Questionnaire, Aug 03
 - VA Form 10-9009F, Depleted Uranium (DU) Program Checklist 24-Hour Urine Uranium
 Collection Baltimore VA Medical Center, Jul 04
 - d. VA DU Specimen Shipping Instructions, 23 Jun 04

Appendix B: DHCC Archiving and Consultation Information

Attachment 3 to ASD (HA) Memorandum, 9 Apr 04, Operation Iraqi Freedom Depleted Uranium Medical Management

DoD Deployment Health Clinical Center (DHCC) medical staff members are available to discuss DU evaluation and management, archiving, case management procedures, including referral to the Baltimore VA, and to provide forms and documents. In additional, all documentation should be forwarded to DHCC, either in hard or electronic copy. Contact information is:

DoD Deployment Health Clinical Center Walter Reed Army Medical Center 6900 Georgia Avenue, NW Bldg 2, Room 3G04 Washington, DC 20307-5001

Clinician Helpline: 1- 866-559-1627 Toll-free from Europe: 00800-8666-8666

Phone: 202-782-6563 DSN: 662-6563 Fax: 202-782-3539

Email: pdhealth@na.amedd.army.mil

Website: www.pdhealth.mil

Baltimore VA DU Medical Follow-up Consultation and Referral Information

The VA medical staff is available to discuss the management of any patient's case with their clinician to provide guidance in follow-up decisions and discussions with the patients. Contact Information is:

Depleted Uranium Follow-up Program

Baltimore VA Medical Center (11DU) 10 N. Greene Street Baltimore, MD 21201 1-800-815-7533

Web site with VA DU Program information: www1.va.gov/gulfwar

Appendix C: Protocol for Urine DU Bioassay Validation Testing and Referrals to the Baltimore VA Follow-up Program

Attachment 2 to <u>ASD (HA) Memorandum, 9 Apr 04, Operation Iraqi</u> Freedom Depleted Uranium Medical Management

24-Hour Urine Samples

- If urine [total U] is < 50 ng/g creatinine (cre) and isotopic analysis indicates presence of DU with or without evidence of embedded fragments, then repeat urine analysis in 6 months.
- 2. If urine [total U] is < 50 ng/g cre and isotopic analysis does not indicate presence of DU, then no follow-up is necessary.
- 3. If urine [total U] is > 50 ng/g cre or isotopic analysis indicates the sample contains DU at 10% or more, then perform urine uranium analysis on a repeat 24-hr urine sample for confirmation.
 - a. If second urine [total U] is still >50 ng/g cre or isotopic analysis indicates presence of 10% or more DU, then complete a radiological skeletal survey to look for evidence of embedded fragments.
 - b. If there is no evidence of embedded fragments on the radiological skeletal survey, then repeat urine DU analysis in 6 months. If still positive after 6 months, the primary care manager first consults with DHCC and, if appropriate, contacts the Baltimore VA for follow-up care.
- 4. If a servicemember has embedded fragments or fragment-type injuries and urine [total U] > 50 ng/g cre and isotopic analysis indicates the presence of DU at 10% or more, primary care manager refers patient to the Baltimore VA In-Patient DU Follow-up Program after consulting DHCC.

Note: all creatinine values used in the calculations to normalize results are urine creatinine concentrations.

Spot Urine Samples

Follow all spot samples with [Total U] > 25ng/g cre with a 24-hour urine test and interpret as above. No follow-up is required for samples with results where [Total U] is < 25 ng/g cre.

Appendix D: OIF DU Exposure Semi-Annual Progress Report

OIF DU EXPOSURE SEMI-ANNUAL PROGRESS REPORT DU Bioassay/Fragment Testing and Results Information

Cumulative Reporting Period: 1 June 2003 through 30 September 2004

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/Phone Numbe
POC (Name
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	# Patients Offered Referral to the VA					
	# Patients Notified of Results					
	Urine DU Detected/ Indicated ⁵					
ay Results	Total Uranium Confirmed ≥50ng/g cre ⁴					
Urine Bioassay Results	Total Uranium Total Uranium Initial Confirmed ≥50ng/g cre ³ ≥50ng/g cre ⁴					
	Total Uranium <50ng/g cre ²					
	Fragment- Type Injury (Q 37)					
	No. Personnel Identified			*		
	Exposure Level	I	Ш	Ш	Uncategorized	Cumulative Totals ⁷

Fragment Information for Patients with Removed Fragments

Patient #	Number of Fragments Removed	Analysis of Each Fragment Removed (attentional sheet if		Urir	Urine Bioassay Results ⁸	ults ⁸		# Patients Offered Referral to the VA
		necessal y)	Total Uranium <50ng/g cre 2	Total Uranium Initial ≥50ng/g cre ³	Total Uranium Confirmed ≥50ng/g cre ⁴	Urine DU Detected/ Indicated	Pending/ Undetermined/ No Sample	
٢								
2								
င								
4								
5								
Cumulative Totals								

Notes:

- Positive response to Question 37a or 37b on the DU Exposure Questionnaire— (DoD Form 2872 Test)
 - Urinalysis < 50ng Total Uranium per gram creatinine
 - Urinalysis ≥ 50 ng Total Uranium per gram creatinine რ
- Urinalysis ≥ 50 ng Total Uranium per gram creatinine, initial and follow up specimens 4.
- Report the criteria used to determine whether the presence of DU was detected or indicated by the bioassay procedures If fragment metal composition is known, identify the major constituents; use a additional sheets if necessary
 - - Cumulative totals will reflect total for the entire reporting period (beginning 30 June 2003)
- Bioassay is only required if the fragment contains DU or if Level I or Level II exposure is suspected or known.
 - * Enter only the number of Level III exposed personnel who received a bioassay.